

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	Li Nie <i>et al.</i>	Examiner	Weier, Anthony J.
Serial No.	10/617,565	Group Art No.	1794
Filed	July 11, 2003	Confirmation No.	3537
For	Grain Protein-Based Formulations And Methods Of Using Same		

December 20, 2008

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER
INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This Information Disclosure Statement is submitted under 37 CFR 1.97(c) together with the \$180 fee under 37 CFR 1.17(p). The Information Disclosure Statement identifies each document by a letter designation for ease of reference. Some of these identifications may be used in later proceedings in this matter.

I. The Wang Rejections

The Examiner has rejected all pending claims of the application under Section 103(a). Each of these rejections involve the Wang publication. All claims are rejected based on Wang with evidence from Kitabatake and, in that context, the Examiner holds that Wang provides a product that is substantially undenatured. Applicants submit that there is not enough disclosure in Wang plus Kitabatake to permit a conclusion that Wang's extruded products are substantially undenatured.

A. Laboratory-Scale Extruders

A simple extruder is a screw in a barrel with a fixed pitch, or distance between threads. The extruder screw rotates in the barrel. The extruder is fed with raw material at one end, which is pushed by the screw down the extruder barrel. The finished formulation, or extrudate, typically is pushed by the extruder through a die that forms the extrudate into useful objects, such as pellets for later use in an injection molding machine.

The extruder can be fitted, usually on the outside surface of the barrel, with heater boxes or jackets to increase the temperature of the formulation as it proceeds through the extruder. Cooling jackets also may be used. Heating and cooling jackets are reasonably effective in controlling formulation temperature in laboratory-scale extruders, which have an internal barrel diameter of an inch or so depending on other variables such as viscosity, RPMs, pressure, etc. This is less true with production-scale extruders. There, the internal volume of the extruder has increased as a function of the barrel radius cubed, while the barrel surface has increased as a function of the barrel radius squared. Heating and cooling jackets are used in industrial extruders to fine tune rather than mediate the temperature of the formulation as it moves down the barrel.

B. The Wang Extruder

The extruder that Wang used in the work discussed in his patent was a Leistritz Micro 18. Information on this extruder is included in the IDS (Cite Nos. HH and KK). The diameter of the barrel was 18 mm. The extruder had 6 heating zones along its length. During Wang's experimental work, the heating zones were set as follows (col 9, lines 61-67):

Zone 1 - about 90° C.

Zone 2 - about 90-100° C.

Zone 3 - about 110° C.

Zone 4 - about 110° C.

Zone 5 - about 90° C.

Zone 6 - about 85° C.

C. Missing Information

Wang lacks important details necessary for the Examiner to conclude that the product was not denatured. For example, in Wang, no information is disclosed about the screw profile. If an aggressive screw profile were used, such as a reverse pitch screw, a common industry practice, substantial denaturation could be occurring. There is also no information about the amount of time the material resided in the extruder, which can also be impacted by the screw profile. Accordingly, applicants submit that the limitation that substantial denaturation must be avoided presents an important distinction over Wang necessary for people skilled in the art to practice the present invention.

II. The Information Disclosure Statement

Most of the documents submitted in the Information Disclosure Statement relate to denaturation issues dealt with by applicants' assignee MGP Ingredients ("MGPI") in patent litigation

filed against Mars Incorporated and S&M NuTec (collectively “Mars”). MGPI’s suit against Mars was filed in 2006 and ended in 2007. The products at issue were the popular dog chews sold under the trademark Greenies®. The grain-protein resins used to make the dogs chews were, until shortly before the lawsuit, made by MGPI for Mars.

The patent in suit was United States Patent No. 5,665,152 (the “152 patent”), which relates principally to the manufacture of thermoplastic resins by extrusion processing. Following is claim 24, one of the two claims principally addressed in the lawsuit:

24. A method of forming protein-containing pellets which can be used in injection molding equipment for the production of biodegradable articles, that method comprising the steps of:

- [A] providing a formulation comprising from about 20-85% by weight of grain protein, from about 5-75% by weight starch, from about 10-40% by weight plasticizer and at least about 0.01% by weight of a reducing agent operable for cleaving disulfide bonds present in said grain protein; and
- [B] heating said formulation and forming said pellets by extrusion, said heating step being carried out so that the formulation [1] heated to a *maximum temperature of up to about 80°C* in the extruder in order to render the formulation [2] *substantially homogeneous and flowable*, with the [3] *avoidance of any substantial heat denaturation* of said grain protein in said pellets.

Relevant elements of part [B] of the claim are emphasized. Paraphrased, the requirements of this part are that the claimed formulation be heated no higher than up to about 80°C to avoid substantial heat denaturation that would prevent the formulation from being substantially homogeneous and flowable

Soon after the pleadings were filed, the Court set a schedule for the litigation and ordered a *Markman* hearing, which took place in August 2006. The submissions to the Court by the parties and the Court’s ruling on claim construction issues following the *Markman* hearing address the denaturation issues in suit. They are a good starting place for the Examiner. The Court’s decision is attached to this document. The decision also is in the IDS, along with the *Markman* submissions by the parties. (Cite Nos. B-E).

There are certain litigation documents that applicants cannot include in the IDS. Production of information in the *Mars* litigation was governed by a Protective Order (Cite No. A). Pursuant to the terms of that Order, MGPI and Mars could produce confidential information to one another on condition that it be used only by the Court, the parties, and their independent experts. As noted, the litigation has now ended, but the Protective Order remains in force. Thus, MGPI is required by law to maintain the confidentiality of Mars’ confidential information.

After discovery was completed in the *Mars* case, both sides filed motions for judgment as a matter of law on various positions taken in the litigation. Issues involving extruder temperatures and denaturation were included in motions for summary judgment on both sides. The IDS includes a few of the papers submitted on the motions for summary judgment (Cite Nos. G- DD), but most are not there. They are under seal with the Court pursuant to the Protective Order. Applicants also are submitting some information relating to laboratory and commercial extrusion hardware (Cite Nos. EE-SS).

III. Conclusion

Should any issues arise in reviewing the IDS, the Examiner is encouraged to telephone the undersigned attorney. Authorization to charge fees associated with this document is submitted herewith. If any additional fee is deemed necessary, please charge Deposit Account No. 12-0600.

Respectfully submitted,

LATHROP & GAGE LC



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